

1647  
TFW

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: MAIL STOP AMENDMENT, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450, ON THE DATE INDICATED BELOW.



BY James H. Rayfield

DATE: October 11, 2004

**PATENT  
MAIL STOP AMENDMENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re:	Patent Application of Yongwon Choi	: Group Art Unit: 1647 : : Examiner: David S Romeo : :
Appln. No.:	10/017,910	: : :
Filed:	December 14, 2001	: Attorney Docket : No. <b>600-1-200 DIV CON</b> : (057832-5004-04) : : :
For:	PROTEIN BELONGING TO THE TNF SUPERFAMILY INVOLVED IN SIGNAL TRANSDUCTION, NUCLEIC ACIDS ENCODING SAME, AND METHODS OF USE THEREOF	: : : : :

**RESPONSE TO RESTRICTION REQUIREMENT**

This response is Responsive to the Restriction Requirement mailed on September 10, 2004 (Paper No. 200409), in connection with the above-captioned application. This Response is being timely filed in view of October 10, 2004 and October 11, 2004, being a Sunday and a Federal holiday, respectively.

**Election of invention**

Responsive to the Restriction Requirement dated September 10, 2004 (Paper No./Mail Date 200409), issued in connection with the above-captioned application, Applicant elects to prosecute claim 65 of Group I, drawn to an antibody that is specific for a polypeptide of SEQ ID NO:2 (human TRANCE protein). This genus election is being made without traverse and without prejudice to the inclusion of the subject matter of the non-elected claims in any later filed divisional or continuation application(s).

Applicant points out to the Examiner that on page 5 of the present Restriction Requirement, claims 10-15 and 60-64 have been deemed to be linking claims which link the

inventions of Group I and Group II. As such, in view of the present election of Group I, claims 10-15 and 60-64 are to be examined with respect to SEQ ID NO:2. Applicant respectfully acknowledges, as pointed out by the Examiner at page 5 of the Restriction Requirement, that upon allowance of any of the linking claims of the presently elected invention, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application.

#### Traversal of species elections

The Examiner has indicated that election of two individual species is required in the response to the present Restriction Requirement. The first species election is directed to the characterization of the antibody as a monoclonal, polyclonal, chimeric, single chain or an Fab fragment of an antibody. The second species election is directed to the manner in which the antibody is detectably labeled, i.e., with alkaline phosphatase, peroxidase or radioactive isotopes.

Applicant herein provisionally elects a monoclonal antibody and alkaline phosphatase. Nonetheless, Applicant traverses the Examiner's Restriction Requirement with respect to the two species elections.

As an initial matter, Applicant respectfully points out to the Examiner that MPEP 803.02 sets forth that if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the Examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not require restriction.

...Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Regarding the first species election directed to the characterization of the antibody as a monoclonal, polyclonal, chimeric, single chain or an Fab fragment of an antibody, Applicant

points out that the five types of antibodies are sufficiently related for the purpose of a prior art search that a search of the term “antibody” having as an immunogen the amino acid sequence as set forth in SEQ ID NO:2 would be able to identify any of these five types of antibodies as set forth in the claims. As such, Applicant respectfully submits that the claims that are directed to the types of antibodies contain sufficiently few members that are closely related for the purpose of a search that searching of these five classes of antibodies will not impose an undue burden on the Examiner.

Regarding the second species election directed to the manner in which the antibody is detectably labeled, i.e., with alkaline phosphatase, peroxidase or radioactive isotopes, Applicant submits that the claims directed to detectable labels also contain sufficiently few types of detectable labels that are closely related for the purpose of a search that searching each of these three types of antibodies will not impose an undue burden on the Examiner.

Further, under the “Guidelines” for restriction requirement practice, the Examiner is required to “provide reasons and/or examples to support conclusions” for the restriction requirement in view of the standard set forth in MPEP 803, which establishes that unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Applicant respectfully submits that the Examiner has not done so regarding the “species election” requirement in the present Restriction Requirement. While it is the Examiner’s stated view that the antibodies directed to the characterization of the antibody as a monoclonal, polyclonal, chimeric, single chain or an Fab fragment of an antibody are patentably distinct species, the Examiner has not provided any evidence or reasons as to why such antibodies are structurally distinct, and why such antibodies are unrelated to one another. Applicant contends that any such antibodies having as an immunogen the amino acid sequence as set forth is SEQ ID NO:2 share a common utility and share a substantial structural feature that is associated to that utility. Thus, in performing a patentability search for an antibody having as an immunogen the amino acid sequence as set forth is SEQ ID NO:2, and in the context of the claims elected herein, the Examiner will necessarily uncover art pertaining to any such antibody, if such art exists. Therefore, no undue burden is placed upon the Examiner to search these types of antibodies at this time. Accordingly, Applicant respectfully requests withdrawal of this election of the species requirement.

Similarly, with respect to the second species election directed to the manner in which the antibody is detectably labeled, i.e., with alkaline phosphatase, peroxidase or radioactive isotopes, Applicant respectfully points out that the Examiner has not provided sufficient evidence or reason as set forth in MPEP 803 for a proper restriction requirement. Applicant submits that in view of current “guidelines” for restriction requirement practice, the Examiner has not provided any evidence or reasons as to why an antibody having as an immunogen the amino acid sequence as set forth is SEQ ID NO:2 that is detectably labeled with any one of the three types of labels are structurally distinct, and why such antibodies are unrelated to one another. As such, the Examiner has not provided evidence or reasons as to why the antibodies as recited in the pending claims with respect to the manner in which the antibodies are labeled are patentably distinct. Applicant contends that any such antibodies having as an immunogen the amino acid sequence as set forth is SEQ ID NO:2 share a common utility and share a substantial structure feature that is associated to that utility. Therefore, in performing a patentability search for an antibody in the context of the claims elected herein, the Examiner will necessarily uncover art pertaining to any such antibody, if such art exists, and therefore would not be an undue burden on the Examiner to search these types of antibodies at this time. Accordingly, Applicant respectfully requests withdrawal of this species election requirement.

Summary

Early consideration and allowance of the claims in the present application is requested at the earliest possible time.

Respectfully submitted,

**YONGWON CHOI**

October 14, 2004  
(Date)

By:

Kathryn Doyle  
**KATHRYN DOYLE, Ph.D., J.D.**

Registration No. 36,317

**MORGAN, LEWIS & BOCKIUS, LLP**

1701 Market Street

Philadelphia, PA 19103-2921

Telephone: (215) 963-5000

**Direct Dial: (215) 963-4723**

Facsimile: (215) 963-5001

E-Mail: [kdoyle@morganlewis.com](mailto:kdoyle@morganlewis.com)

Attorney for Applicants

KD/QDN *del*